



PATENT
Attorney Docket No. CASE-02138

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Paul V. Lehmann *et al.*

Serial No.: 08/621,725

Filed: 03/21/96

Entitled: METHODS FOR INDUCING IMMUNITY

Group No.: 1644

Examiner: R. Schwadron

INFORMATION DISCLOSURE
STATEMENT TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)	
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Dated: <u>October 17, 2003</u>	By: <u>Mary Ellen Waite</u> Mary Ellen Waite

Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: October 17, 2003

Jason R. Bond
Jason R. Bond
Registration No. 45,439

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101 Howard Street, Suite 350
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10/23/2003 ANAB11 00000047 08621725 180.00 DP
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The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- U.S. Patent No. 4,948,442 to Roy Manns;
- U.S. Patent No. 5,047,215 to Roy Manns;
- D.E. Smilek *et al.*, "Antigen Recognition and Peptide-Mediated Immunotherapy in Autoimmune Disease," *Immunol. Rev.* 118:37-71 (1990);
- Raine, C.S., 1983, *Multiple Sclerosis -- Pathology, Diagnosis, and Management*, J. Hallpike, C.W.M. Adams, W.W. Tourtelotte (Eds.) (London: Chapman & Hall)(1983);¹

¹ We were unable to locate this reference. If the examiner requests, we will seek to obtain it.

- E. Alvord, *Experimental Allergic Encephalomyelitis: A Useful Model for Multiple Sclerosis, Progress in Clinical and Biological Research*, E.C. Alvord *et al.* (Eds.) (New York, NY) (1984)²;
- S. Zamvil and L. Steinman, "The T Lymphocyte In Experimental Allergic Encephalomyelitis," *Ann. Rev. Immunol.* 8:579-621(1990);
- J. Kimball, Introduction to Immunology (2d Edition) Macmillan Publishing, NY p. 488 (1986);
- Goodman and Gilman's, The Pharmacological Basis of Therapeutics (8th Edition) Pergamon Press, p.1270;
- I. Roitt *et al.*, Immunology, section 8.9, Gower Medical Publishing, London (1985);
- B. Katzung, Basic & Clinical Pharmacology (5th Edition), Appleton & Lange, Norwalk, Ct ,p. 537 (1992);
- R.R. Caspi *et al.*, "A New of Autoimmune Disease, Experimental Autoimmune Uveoretinitis Induced in Mice with Two Different Retinal Antigens," *J. Immunology* 140: 14901495 (1988);
- B. Marshall, "Unidentified Curved Bacilli on Gastric Epithelium in Active Chronic Gastritis," *Lancet* 1:1273-1275 (1983);
- M.J. Blaser, *Prin. Pract. Infect. Dis.*, pp. 3-10 (1991);³
- A. Lee *et al.*, "Isolation of a Spiral-Shaped Bacterium from the Cat Stomach," *Infect. Immun.* 56:2843-2850 (1988); and
- B.J. Paster *et al.*, "Phylogeny of *Helicobacter felis* sp. nov., *Helicobacter mustelae*, and Related Bacteria," *Int'l. J. Sys. Bacteriol.* 41:31-38 (1989).

Applicants have become aware of the following printed publications which may be material to the examination of this application:

² This reference was cited in the application as a general text book without any direction to the page(s) and therefore no excerpts are included in PTO1449.

³ We were unable to locate this reference. If the examiner requests, we will seek to obtain it.

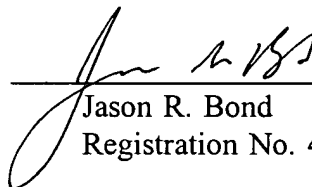
- E.R. Einstein *et al.*, "Protective Action of the Encephalitogen and Other Basic Proteins in Experimental Allergic Encephalomyelitis," *Immunochemistry* 5:567-575 (1968)
- S. Waksal, *Immunology II*, W.B. Saunders Company, Philadelphia (Ed. J.A. Bellanti) pp. 243-250 (1978)
- C.W.M. Adams, "The General Pathology of Multiple Sclerosis: Morphological and Chemical Aspects of the Lesions," Multiple Sclerosis -- Pathology, Diagnosis, and Management, [J. Hallpike *et al.* (Eds.)] (London: Chapman & Hall) Chapter 8 pp.203-240(1983)
- S. Liebowicz, "The Immunology of Multiple Sclerosis," Multiple Sclerosis -- Pathology, Diagnosis, and Management, [J. Hallpike *et al.* (Eds.)] (London: Chapman & Hall) Chapter 12 pp.379-412 (1983)
- D. Male *et al.*, Advanced Immunology, Gower Medical Publishing, London (1991)
- R.J. Trauger, "Effect of Immunization with Inactivated gp-120-Depleted Human Immunodeficiency Virus Type 1 (HIV-1) Immunogen on HIV-1 Immunity, Viral DNA, and Percentage of CD4 Cells," *J. Infectious Dis.* 169:1256-64 (1994)
- R.R. Caspi *et al.* "Endogenous Systemic IFN- γ Has a Protective Role against Ocular Autoimmunity in Mice," *J. of Immunology* 152:890 (1994) c protein and incomplete Freund's Adjuvant to treat multiple sclerosis.
- G. Pialoux *et al.*, "A Prime-Boost Approach to HIV Preventative Vaccine Using a Recombinant Canarypox Virus Expressing Glycoprotein 160 (MN) followed by a Recombinant Glycoprotein 160 (MN/LAI)," *Aids Research and Human Retroviruses* 11:373-381(1995)
- Swierkosz *et al.*, "Antibody response in the prevention and induction of experimental allergic encephalomyelitis (EAE) in Lewis rats," *Immunology* pp.814 (abstract)⁴

4 We are unable to determine the full citation for this reference, if the examiner request the full citation we will seek to obtain it.

- Selected methods in cellular immunology, Mishell and Shiigi, eds., W.H. Freeman and Co., San Francisco, pp.467 (1980)
- "Difco Manual: Dehydrated culture media and reagents for microbiology", 10th ed. Difco Lab. Detroit, MI p.67-68, 468 (1984)
- Merck Manual, "Hematology and Oncology," 16th ed., p. 1292 (1992)
- Merck Manual, 16th ed., pp 1106-1113, 1305-1312, 1487-1490 and 1900-1901 (1992)
- Offner *et al.*, "T cell receptor peptide therapy triggers autoregulation of experimental encephalomyelitis" *Science* 251:430-432 (1991)
- Vandenbark *et al.*, "Immunization with a synthetic T cell receptor V-region peptide protects against experimental autoimmune encephalomyelitis" *Nature* 341:541-544 (1989)
- Viselli *et al.*, Detection and quantitation of interleukin-2 from individual cells, *J. Immun. Methods* 125:115-124 (1989)

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: October 17, 2003



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FORM PTO-1449
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Attorney Docket No.: CASE-02138

Serial No.: 03/21,725

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Include all relevant documents, even if they are not cited in the application)

(37 CFR § 1.98(b))

Applicant: Paul V. Lehmann *et al.*

Filing Date: 03/21/96

Group Art Unit: 1644

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	4,948,442	08/14/90	Roy Manns	156	73.1	06/18/85
	2	5,047,215	09/10/91	Roy Manns	422	101	05/30/90

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

/	3	D.E. Smilek <i>et al.</i> , "Antigen Recognition and Peptide-Mediated Immunotherapy in Autoimmune Disease," <i>Immunol. Rev.</i> 118:37-71 (1990)
/	4	S. Zamvil and L. Steinman, "The T Lymphocyte In Experimental Allergic Encephalomyelitis," <i>Ann. Rev. Immunol.</i> 8:579-621(1990)
/	5	J. Kimball, <i>Introduction to Immunology</i> (2d Edition) Macmillan Publishing, NY p. 488 (1986)
/	6	Goodman and Gilman's, <i>The Pharmacological Basis of Therapeutics</i> (8th Edition), Pergamon Press (p.1270)
/	7	I. Roitt <i>et al.</i> , <i>Immunology</i> section 8.9, Gower Medical Publishing, London (1985)
/	8	B. Katzung, <i>Basic & Clinical Pharmacology</i> (5th Edition), Appleton & Lange, Norwalk, Ct, p. 537 (1992)
/	9	R.R. Caspi <i>et al.</i> , "A New of Autoimmune Disease, Experimental Autoimmune Uveoretinitis Induced in Mice with Two Different Retinal Antigens," <i>J. Immunology</i> 140:1490-1495 (1988)
/	10	B. Marshall, "Unidentified Curved Bacilli on Gastric Epithelium in Active Chronic Gastritis," <i>Lancet</i> 1:1273-1275 (1983)
/	11	A. Lee <i>et al.</i> , "Isolation of a Spiral-Shaped Bacterium from the Cat Stomach," <i>Infect. Immun.</i> 56:2843-2850 (1988)
/	12	B.J. Paster <i>et al.</i> , "Phylogeny of <i>Helicobacter felis</i> sp. nov., <i>Helicobacter mustelae</i> , and Related Bacteria," <i>Int'l. J. Sys. Bacteriol.</i> 41:31-38 (1989)
/	13	E.R. Einstein <i>et al.</i> , "Protective Action of the Encephalitogen and Other Basic Proteins in Experimental Allergic Encephalomyelitis," <i>Immunochemistry</i> 5:567-575 (1968)
/	14	S. Waksal, "Immunomodulation: Immunopotential, Tolerance, and Immunosuppression," <i>Immunology II</i> , W.B. Saunders Company, Philadelphia (Ed. J.A. Bellanti) pp. 243-250 (1978)
/	15	C.W.M. Adams, "The General Pathology of Multiple Sclerosis: Morphological and Chemical Aspects of the Lesions," <i>Multiple Sclerosis -- Pathology, Diagnosis, and Management</i> , [J. Hallpike <i>et al.</i> (Eds.)] (London: Chapman & Hall) Chapter 8 pp.203-240(1983)
/	16	S. Liebowicz, "The Immunology of Multiple Sclerosis," <i>Multiple Sclerosis -- Pathology, Diagnosis, and Management</i> , [J. Hallpike <i>et al.</i> (Eds.)] (London: Chapman & Hall) Chapter 12 pp.379-412 (1983)
/	17	D. Male <i>et al.</i> , <i>Advanced Immunology</i> , Gower Medical Publishing, London (1991)
/	18	Merck Manual, "Hematology and Oncology," 16th ed., p. 1292 (1992)
/	19	R.J. Trauger, "Effect of Immunization with Inactivated gp-120-Depleted Human Immunodeficiency Virus Type 1 (HIV-1) Immunogen on HIV-1 Immunity, Viral DNA, and Percentage of CD4 Cells," <i>J. Infectious Dis.</i> 169:1256-64 (1994)
/	20	R.R. Caspi <i>et al.</i> "Endogenous Systemic IFN- γ Has a Protective Role against Ocular Autoimmunity in Mice," <i>J. of Immunology</i> 152:890-899 (1994)
/	21	G. Pialoux <i>et al.</i> , "A Prime-Boost Approach to HIV Preventative Vaccine Using a Recombinant Canaripox Virus Expressing Glycoprotein 160 (MN) followed by a Recombinant Glycoprotein 160 (MN/LAI)," <i>Aids Research and Human Retroviruses</i> 11:373-381(1995)
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/	23	<i>Selected methods in cellular immunology</i> , Mishell and Shiigi, eds., W.H. Freeman and Co., San Francisco, pp.467 (1980)
/	24	"Difco Manual: Dehydrated culture media and reagents for microbiology", 10 th ed. Difco Lab. Detroit, MI p.67-68, 468 (1984)
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/	26	Offner <i>et al.</i> , "T cell receptor peptide therapy triggers autoregulation of experimental encephalomyelitis" <i>Science</i> 251:430-432 (1991)
/	27	Vandenbark <i>et al.</i> , "Immunization with a synthetic T cell receptor V-region peptide protects against experimental autoimmune encephalomyelitis" <i>Nature</i> 341:541-544 (1989)

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Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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(37 CFR § 1.98(b))

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OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

28	Raine, C.S., 1983, <i>Multiple Sclerosis -- Pathology, Diagnosis, and Management</i> , J. Hallpike, C.W.M. Adams, W.W. Tourtelotte (Eds.) (London: Chapman & Hall)(1983)
29	E. Alvord, <i>Experimental Allergic Encephalomyelitis: A Useful Model for Multiple Sclerosis, Progress in Clinical and Biological Research</i> , E.C. Alvord <i>et al.</i> (Eds.) (New York, NY) (1984)
30	Viselli <i>et al.</i> , Detection and quantitation of interleuken-2 from individual cells, <i>J. Immun. Methods</i> 125:115-124 (1989)
31	M.J. Blaser, <i>Prin. Pract. Infect. Dis.</i> , pp. 3-10 (1991)

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